

**DSJ1&2-PR Exh 547**

**Debbie Komoroski**

---

From: Kathleen Cross  
Sent: Wed 10/15/2014 4:46 PM (GMT-04:00)  
To: Debbie Komoroski; Tracey Hernandez  
Cc:  
Bcc:  
Subject: Debbie, Please call Tracey at the phone number of [REDACTED] She is expecting your call right now. Thanks for the last minute.  
Attachments: SOMs Experience.docx; Resume\_of\_Tracey\_Hernandez[1].docx

*(See attached file: SOMs Experience.docx)*

*(See attached file: Resume\_of\_Tracey\_Hernandez[1].docx)*

Kathleen Cross, MA, SPHR  
Talent Management Specialist/Corporate Recruiter  
H. D. Smith  
3201 W. White Oaks Drive, Suite 203B  
Springfield, IL 62704  
Office: 217.467.8932  
Fax: 217.391.2891  
Kathleen.cross@hdsmith.com  
Helping You Care For Your Community

## **Tracey Hernandez**

### **SUMMARY OF SUSPICIOUS ORDER MONITORING (SOM) EXPERIENCE**

NOTE: Experience with SOM has evolved with each new position as DEA's requirements have also evolved over time.

#### **Ciba-Geigy/Novartis:**

Responsible for conducting internal audits of Customer Service Department (as well as many other departments including distribution centers), to assure that customer licensing was obtained and verified. Modified process to include the use of the NTIS tape to assure license checks occurred at each order, rather than depending on customers to provide new license at expiry. Increased awareness and allowed for earlier action when a customer's license was suspended or revoked. Reviewed and submitted monthly suspicious order monitoring reports to DEA for their review – back then, suspicious orders were based solely on the customer's order frequency, pattern and volume. Notified Customer Service based on DEA Federal Register Notices or conversations with DEA if a customer was deemed high risk and should be discontinued.

#### **Watson:**

Conducted internal audits as noted above. Watson already utilized NTIS but based on the requirements of several states, added the process for collecting customer state license information. As part of the internal audits, began to run shipping history for certain customers of concern. Customer Service still handled the day to day operation of the SOM program but Watson's program included a multiplier and it was my sole responsibility to adjust that multiplier, to add certain products to SOM control (i.e. pseudoephedrine products, carisoprodol before it became controlled by DEA) and to assure that the program met DEA requirements. Watson had no issues with DEA regarding their SOMs program during my seven year tenure. However, Watson purchased Anda and shortly afterward, Anda was summoned to DEA as a result of their lack of a robust SOM program. I did not support Anda from a DEA perspective as they had come to Watson with their own DEA person. However, I was asked to be their DEA representative for the meeting in HQ. I went with Legal and the individual who at the time was the President of Anda. DEA presented and provided a binder as they have done for most companies at this point. However, in Anda's case, the DEA meeting was for cause and immediate action was required. I worked with the President and we reviewed numerous customers and cut many. Anda revamped their program and we conveyed the results to DEA. No violation was received. Prior to my leaving, I was instrumental in convincing Watson to start

looking at drug combinations (i.e. Holy Trinity), and to begin customer visits for the purpose of SOM which I believe they now contract out to a third party.

**Qualitest:**

Upon arrival at Qualitest, I did not have responsibility for SOMs. The program reported into Sales and it was basically managed by two individuals; no customer visits occurred other than sales visits. Without going into detail, at the time, the program was minimal at best. Historical files showed that Qualitest had had two separate incidents with DEA which led to their discontinuation of shipments direct to physicians and limited products they could ship direct to independent retailers. I was very concerned with the status of the program and began to work with Sales, Customer Service and IT to make improvements and with my management to raise my concerns. NTIS and State license checks were added, Sales began to come to me regarding orders of interest and after gathering information with them, some customers were discontinued and reported to DEA. I also worked closely with the Director of Security and we continually shared information we obtained regarding geographical diversion issues. I gained additional diversion information through NADDI/DEA conferences and through my position as a Board Member for the Partnership for a Drug Free Community in Huntsville/Madison County. The Partnership meetings are attended by approximately 70% law enforcement and have also been attended by the AL Special Agent In Charge, Clay Morris.

In early 2013, I received approval to move the SOM program into DEA Compliance. To make immediate improvements, we contracted with two third parties. One contractor had the algorithm for our orders to run through and was capable of linking to our order management system. The second allowed for the extraction of massive amounts of data from various locations to be fed into a dashboard for ease of viewing. Sales and chargeback data are both used. The dashboard allows for geographical and product specific or product combination analysis as well as customer and class of trade reviews. Lastly, we contracted with a third party to conduct customer visits but later found that having them conducted by our own team was more customer friendly, had longer term benefit and allowed us to gather more information.

The program has also been built to have layers and customers that may pass the algorithm check are also checked against a predetermined boundary based on national dispensing data obtained from IMS and information gained from their questionnaires. The combination of all of these activities allows us to know not only our direct customers but our customers' customers.

My SOMs group is made up of an individual from the Sales team that I thought had the capability to wear both the compliance and sales hat simultaneously and a Manager I brought in from one of the major wholesalers. We also use one temporary headcount who has a regulatory background and rely on our Legal, Sales and an internal physician's expertise.

Implementation of the program involved obtaining buy in of Sr. Level Management in Operations, Supply, Finance, Distribution, Customer Service, Legal, Security, Sales and Marketing and Corporate Ethics; many of whom had no knowledge whatsoever of DEA or the SOM requirements. Rollout of the program required training of all personnel in each of these areas. My oversight of the program includes review, comment and sign off of all SOMs SOPs and training, and directing of the content. These activities also included implementation of a new customer questionnaire and letters that were sent to each customer at the start of the program. DEA inspected the program earlier this year and not only had no concerns but complimented certain aspects of the program.

**Generally:**

- Member of the Anti-Diversion Working Group (Mallinckrodt, Actavis, Amerisource, Cardinal, McKesson & HD Smith belong); group supported the creation of the Red Flags Video for Pharmacists currently available on NABP, NADDI and various State Board of Pharmacy websites.
- Long term member of NADDI. Please confer with Charlie Cichon for a reference.
- Long term participant in NASCSA conferences and consulted for the group on the group to obtain information from State authorities regarding their licensing and PMP requirements. This information can be seen on NASCSA's website under "State Profiles".
- Masters Program – included review of several law cases involving pharmacies and pharmacists under fire by DEA for their actions. Familiar with the "Chilling Affect". Program was run by a pharmacist/attorney who can also provide a reference (David Brushwood, RPh, JD).
- Attended DEA conferences over the years on a regular basis including the recent Distributors Conference. Extensive interaction with local and HQ offices to gain understanding of their position on SOMs.
- Was recently asked to present at the Cegedim Conference in Orlando in late October 2014. Presentation topic: Suspicious Order Monitoring.

NOTE: Please treat as confidential information.

**TRACEY L. HERNANDEZ**

6735 McEachern Lane SE  
Huntsville, AL 35763  
[REDACTED]

**OBJECTIVE:** To be a leader in the pharmaceutical industry specializing in DEA, PDMA and/or State compliance initiatives.

**EXPERIENCE:**

8/2011-present *Qualitest Pharmaceuticals, Inc., 130 Vintage Drive, Huntsville, AL 3563*

Director, DEA Compliance

- Member of the Operations Leadership Team responsible for key decisions and strategic initiatives for the Huntsville, AL and Charlotte, NC sites.
- Responsible for all aspects of DEA Compliance for these facilities.
- Development of the complete DEA program including design, hiring and mentoring of DEA Compliance group members, creation of an operational structure within Manufacturing and the Warehouse to prevent diversion, design of the employee training plan, oversight of DEA reporting, quota and SOP creation, providing guidance on ERP and WMS systems, creation of strategic plans and risk management assessments.

3/2010-8/2011 *Reckitt Benckiser, Inc., 399 Interpace Parkway, Parsippany, NJ 07054*

Compliance Manager, Regulatory Affairs Department

- Responsible for developing a compliance program to assure all sample activities regulated by FDA's Prescription Drug Marketing Act were met (for Reckitt Benckiser this included List I chemicals also regulated by DEA)
- System validation of Target Mobile System for Sales Representatives
- Coordinated all State compliance activities related to wholesale distribution of medical devices, OTC products, cosmetics, controlled substances and List I chemicals.
- Interpreting State aggregate spend requirements and developing the company's program for compliance which included several revisions to the expense reporting system Concur. Roll-out and training on same.
- Compliance officer responsibilities as described in the OIG Compliance Program Guidance including the False Claims Act and Federal Anti-Kickback Statute.

6/2002-8/2009 *Watson Laboratories, Inc., 360 Mt. Kemble Avenue, Morristown, NJ 07962*

Director of Controlled Substance Compliance

- Managed the controlled substance activities of eleven different manufacturing, research, analytical laboratory and distribution facilities, including four to six direct reports and a budget of just over \$1M
  - Signatory authority for import/export permits and declarations, 222 order forms and registrations that did not require a Corporate Officer
  - Responsible for overseeing State, DEA and VAWD requirements, including fingerprinting, surety bonds, home state verifications and designated representatives
  - Designed database to manage 400+ DEA and State Registrations (dist., mfg., sales)
  - Supervised the internal audit function which performed routine site assessments that led to significant compliance improvements (DEA, PDMA, GMP, Ethics, Investigations)
- Performed complex analysis of existing regulations and pending federal legislative bills; recognized resident subject matter expert on DEA regulations
  - Suspicious Order Monitoring
  - Ryan Haight Act – Internet Pharmacies
  - Electronic Prescribing

Tracey L. Hernandez  
Resume – Page 2

- Drug Disposal Initiatives
- Prepared detailed analytical summaries and timely responses to industry-related issues that had a direct impact on the company's business model and profitability
  - Researched and authored position paper that led to the development of the company's controlled substance import strategy
  - Created talking points and presentations utilized in high level quota negotiations and compliance matters with DEA and State agencies
  - Developed and delivered proactive, timely and results-driven training for employees at all levels
  - Collaborated with others in industry to drive favorable policy formation
- Provided guidance and refined the company's regulatory policy through the authoring of several standard operating procedures:
  - Theft/loss reporting, tableting & encapsulating machine transfers, 222 form processing, registration processing, internal audits, quota requests, ARCOS reporting, imports and exports, etc.
- Oversaw and directed quota applications for Schedule II and List I chemicals
  - Supervised the development of spreadsheets to effectively track purchases, quota requests, approvals, sales and forecasts for commercial products
- Successfully completed several product development, scale-up and/or transfer initiatives with no compliance issues
- Represented the organization with federal and state regulatory agencies
  - Established liaison for site inspections
  - Excellent rapport with members of DEA Field and HQ Offices
  - Collaborated with other departments to assure understanding of business and logistical implications of any findings or concerns
- Gained valuable contacts through peer groups and industry associations

4/1987-6/2002 *Novartis Pharmaceuticals, Inc. 59 Route 10, East Hanover, NJ 07936*

DEA/PDMA Manager (1997–2002)

- Provided a primary contact for the Pharmaceuticals Division with federal agencies such as the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) on all issues concerning the Controlled Substances Act of 1970 and the Prescription Drug Marketing Act (PDMA) of 1988.
- Acted as a consultant to the division for issues associated with these regulations (i.e. quota, ARCOS, import/export, 222 forms, in-transit losses/thefts, returns/disposals, etc.).
- Interpreted and applied existing regulations and reviewed and monitored proposed rulemaking
- Performed internal audits, inventories and investigations of applicable departments at all three sites and external audits of suppliers, contract packagers and fulfillment houses.
- Actively participated in investigations related to potential diversion and/or the performance of sales representatives
- Coordinated DEA or FDA inspections pertinent to these regulations at all three sites
- Supervised development of controlled drug reporting systems such as ARCOS or SOMs (Suspicious Order Monitoring)
- Submitted theft and/or loss reports to DEA/FDA
- Served on various project teams (e.g. Ritalin Batch Record Project Team, Warehouse Integration Team)
- Participated in the creation of print materials for multiple controlled product Education Campaigns (input, review, approval, dissemination)
- Supervised DEA/PDMA Specialist

Tracey L. Hernandez  
Resume – Page 3

Compliance Analyst I/II (1992-1997)

- Sole trainer for the Pharma Division in DEA regulations
- Coordinated DEA and State Registrations
- Oversaw, and in some cases conducted yearly controlled substance inventories for three sites
- Submitted various reports to DEA, FDA or State agencies.

Regulatory Analyst (1989-1992)

- Prepared and submitted promotional material to the FDA
- Assured the accurate submission of Drug Listings to FDA for all products
- Maintained the customer complaint database for all products (both medical and technical)
- Worked with various regulatory agencies to resolve import issues

**EDUCATION:**

- Seton Hall University, South Orange, NJ – Corporate Healthcare Compliance Certificate – 2010
- University of Florida, Gainesville, FL - Masters in Pharmacy (Pharmaceutical Policy & Regulation) - May 2010. Courses focused on brand/generic drug approval, FDA, DEA and State regulations, Risk Evaluation and Mitigation Strategies (REMS), DDMAC/promotion and advertising, Medicare/Medicaid and private insurance, quality of care initiatives, comparative effectiveness testing and case law supporting each. GPA: 4.0
- Muhlenberg College, Easton, PA - B.A., Business Administration, with honors – 2001. GPA: 3.8
- ASQ Certified Quality Auditor (CQA)
- AQP Certified Facilitator

**ASSOCIATIONS:**

NADDI Member, Member of the NASCSA 2009 Resolutions Committee, Midwest Discussion Group Member, NJ Pharmaceutical Industry Working Group

**REFERENCES:** Available upon request.